

§51.7 Dispute resolution process.

(a) *In general.* Upon receipt of its preliminary fee calculation, each covered entity will have an opportunity to dispute this calculation by submitting to the IRS an error report as described in this section. The IRS will provide its final determination with respect to error reports no later than the time the IRS provides a covered entity with a final fee calculation.

(b) *Error report information.* To assert that there have been one or more errors in the drug sales data reported by a Program, the mathematical calculation of the fee, the rebate data, the listing of an NDC for an orphan drug, or any other error, a covered entity must submit an error report with each asserted error reported on a separate line. The report must include the following information—

(1) Entity name, address, and Employer Identification Number (EIN) as previously reported on the Form 8947;

(2) The name, telephone number, fax number, and email address (if available) of one or more employees or representatives of the entity with whom the IRS may discuss the claimed errors. If the representative is not an employee of the covered entity who is authorized under section 6103 or designated on Form 8947 to discuss the information reported on Form 8947 with the IRS, a Form 2848, “Power of Attorney and Declaration of Representative,” must be filed with the error report;

(3) For an error in the drug sales data reported by a Program, the name of the Program that reported the data, the NDC, the specific amount of sales data disputed, the proposed corrected amount, an explanation of why the Agency should use the proposed corrected data instead, and documentation of any Program drug sales data or other information used to establish the existence of any errors.

(4) For a mathematical calculation error, the specific calculation element(s) that the entity disputes and its proposed corrected calculation;

(5) For a rebate data error, the NDC for the drug to which it relates; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on

rebates; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(6) For the listing of an NDC for an orphan drug, the name and NDC of the orphan drug; a discussion of whether the data used in the preliminary fee calculation matches previously reported Form 8947 data on orphan drugs; and, if the data used in the preliminary fee calculation does match the Form 8947 data, an explanation of why the Form 8947 data was erroneous and why the IRS should use the proposed corrected data instead;

(7) For any other asserted error, an explanation of the nature of the error, how the error affects the fee calculation, an explanation of how the entity established that an error occurred, the proposed correction to the error, and an explanation of why the IRS or Agency should use the proposed corrected data instead;

(8) If an entity is using data to establish the existence of an error and that data was not reported on Form 8947 or contained in the notification of the preliminary fee calculation, a description of what the data is, how the entity acquired the data, and who maintains it; and

(9) Documentation of any rebate and orphan drug data, or other information used to establish the existence of any errors.

(c) *Form, manner, and timing of submission.* Each covered entity must submit its error report(s) in the form and manner that is prescribed in guidance published in the Internal Revenue Bulletin. This guidance will also prescribe the date by which each covered entity must submit its report(s).

(d) *Finality.* A covered entity must assert any basis for contesting its preliminary fee calculation during the dispute resolution period. In the interest of providing finality to the fee calculation process, the IRS will not accept an error report after the end of the dispute resolution period or alter the final fee calculation on the basis of information provided after the end of the dispute resolution period.

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